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Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF CHAIN DRUG STORES IN SUPPORT OF PETITIONERS

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Bonito Boats, Inc. v. Thundercraft Boats, Inc., 489 U.S. 141 (1989) 19

Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993) 16, 18, 19

Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451 (1992) 5

eBay Inc. v. Mercexchange, L.L.C., 126 S. Ct. 1837 (2006) 14, 16, 17

Geneva Pharm. Tech. Corp. v. Barr Labs., Inc., 386 F.3d 485 (2d Cir. 2004) 19

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Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679 (Fed. Cir. 1990) 15

Imperial Chem. Indus., PLC v. Barr Labs., Inc., 795 F. Supp. 2d 619 (S.D.N.Y. 1992) 17, 18

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In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004) .. 7

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Laboratory Corp. of America Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) 16, 19

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Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120 (D.C. Cir. 2006) 17

Cited Authorities

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Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552 (Fed. Cir. 1994) 15

Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) 3, 9, 13, 15

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SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331 (Fed. Cir. 2005) 10

Standard Oil Co. (Indiana) v. United States, 283 U.S. 163 (1931) 6, 7

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983) 14

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United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001) 13

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004) 4, 5

Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, L.L.P., 540 U.S. 398 (2004) 13

Cited Authorities

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Zeneca Ltd. v. Novapharm Ltd., 111 F.3d 144 (Fed. Cir. 1997) 18

Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100 (1969) 14

Statutes:

The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355) 2

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 15

21 U.S.C. § 355 ..... 2, 7, 14, 17

35 U.S.C. § 282 ....4, 8, 13

Other Authorities:

146 CONG. REC. E1538-02 (daily ed. Sep. 20, 2000) .. 15

147 CONG. REC. S3711 (daily ed. Apr. 6, 2001) 15

148 CONG. REC. S7566 (daily ed. Jul. 20, 2002) ... 15

Abbott Labs. and Geneva Pharms., No. C-3945, (FTC Mar. 16, 2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary), *available at http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.html* 11

Cited Authorities

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John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998) 4

FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at http://www.ftc.gov/os/2002/07genericdrugstudy.pdf* .. 2

FTC, *Prepared Statement of the Federal Trade Commission* (Jan. 17, 2007), *available at http://www.ftc.gov/speeches/leibowitz/07170/oralstatement.pdf* 11

FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Oct. 2003), *available at http://ftc.gov/os/2003/10/innovationrpt.pdf* 4

XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 2030b (2d ed. 2005) 13

Herbert Hovenkamp et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIES TO INTELLECTUAL PROPERTY LAW § 7.4 (2006 Supp.) .. 19

Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003) 6, 12

Herbert Hovenkamp et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712 (2004) 13

Cited Authorities

Page

Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Quart. J. 1 (2006) 2

William M. Landes, *An Economic Analysis of Courts*, 14 J. L. & Econ. 61 (1971) 6

Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holders Should Be Per Se Illegal*, 21 Res. L. & Econ. 475 (2004) 12

Keith Leffler et al., *Efficiency Trade-Offs In Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F.L. Rev. 33 (2004) 5, 10, 11

Bethany McLean, *A Bitter Pill*, Fortune, Aug. 2001 10

Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. of Econ. 391 (Summer 2003) 6

STATEMENT OF INTEREST OF AMICUS CURIAE

The National Association of Chain Drug Stores ("NACDS") is a non-profit association of nearly 200 retail pharmacy chains. NACDS members operate more than 36,000 retail community pharmacies and dispense approximately 70% of Americans' prescription drugs. Anticompetitive practices by drug manufacturers, such as the practice at issue in this case, harm NACDS members and their customers by maintaining artificially high prices for prescription drugs. NACDS believes that its industry-wide perspective on this important issue will be of assistance to the Court and therefore submits this *amicus curiae* brief in support of the petition for writ of certiorari to the United States Court of Appeals for the Second Circuit.[1]

The Second Circuit panel held that the patentee lawfully paid a challenger to withdraw its challenge to the patent and to significantly restrict competition. If left standing, that decision would undermine a careful statutory scheme in which Congress sought to rid the pharmaceutical marketplace of weak or narrow patents that block generic entry. Given the enormous consequences for consumers — consumers whose elected representatives reached a starkly different balance between the interests of patent holders and consumers — review by this Court is appropriate.

BACKGROUND

Generic entry poses a unique competitive threat to brand pharmaceuticals. Generics typically enter the market at a steep discount to the brand price, and the brand may lose as much as 70% of unit sales within the first few months after generic entry.

Manufacturers of branded pharmaceuticals therefore have a strong financial incentive to obtain patents on their products

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1. The written consents of all parties to the filing of this brief have been filed with the Clerk. No counsel for a party has authored this brief in whole or in part, and no person or entity other than *amicus curiae*, its members, or its counsel has made a monetary contribution to the preparation or submission of this brief.

and to sue generic firms to keep them out of the market. The Hatch-Waxman Act[2] encouraged generic entry by providing that the FDA cannot approve any additional generics until 180 days after the approval of the first generic whose application certified that the asserted patent is invalid or not infringed. 21 U.S.C. §355(j)(5)(B)(iv). This financial "bounty" granted by Congress for generic entry through a patent challenge can be worth hundreds of millions of dollars for the "first-filer" on blockbuster drugs. *See Teva Pharm. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 180 (D.D.C. 2005).

Congress' program of encouraging generic entry through patent challenges was a huge success. Of such cases litigated to conclusion, 73% have been resolved in favor of the generic challenger. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 16 (July 2002), *available at http://www.ftc.gov/os/2002/07genericdrugstudy.pdf*; *see also* Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Quart. J. 1, 20 (2006) (generic challengers win 70%).

Some pharmaceutical manufacturers have responded to their poor showing in these cases by paying the generic firm to withdraw the patent challenge and stay out of the market altogether, or to stay out longer than the strength of the patent warrants. By paying cash to the generic firm not to enter or to restrict entry, the patentee obtains exclusion based not on the strength of its patent, but on the strength of its capital. By accepting cash to restrict competition, the generic firm makes returns not by earning profits on sales, but by agreeing *not* to make sales in exchange for a share of the resulting monopoly rents.

The Second Circuit here nevertheless held that such "exclusion payment" settlements are (with few exceptions) per se *lawful* under Section 1 of the Sherman Act. As set forth in detail below, review by this Court is necessary because of the

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2. The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355).

clear and irreconcilable split between the Circuits, the enormous consequences of the Second Circuit's decision for consumers, and the incompatibility of that decision with the Hatch-Waxman Act and this Court's patent law precedents.

DISCUSSION

I. The Circuits Are Split Over The Fundamental Antitrust Issue — The Proper Competitive Baseline.

The exclusion payment settlement here permitted the generic firm to enter, but with a very high royalty rate that prevented the generic product from being discounted more than 5% below the price of the branded product. Pet. App. at 58a. Absent the royalty-rate constraint, the first generic entrant typically enters at a price at 20% - 30% below the brand. In *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1059 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006), the exclusion payment agreement required the generic firm to stay out of the market altogether for more than four years. In another case, in exchange for exclusion payments of $398 million, the generic firm stayed out of the market for 6 1/2 of the remaining 7-year life of the patent. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519 (E.D.N.Y. 2005), *appeals docketed*, Nos. 05-2851, 05-2852, 05-2863 (2d Cir.). The fundamental antitrust question raised by these cases is whether exclusion payment agreements result in less competition than is likely to result absent the exclusion payments. To answer that question, courts must estimate how much competition is likely to result absent the exclusion payments. This is the fundamental issue over which the Circuits are hopelessly split: what is the competitive baseline against which the exclusion payment settlements are properly measured?

This inquiry starts with the fact that it is uncertain whether and how much competition would result from patent litigation. Infringement determinations are usually fact intensive and subject to great uncertainty. And the question of patent invalidity is "as fugitive, impalpable, wayward, and vague a phantom as

exists in the whole paraphernalia of legal concepts." *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir. 1950) (Hand, C.J.).

The uncertainty stems in large part from the fact that patents do not receive anywhere near the scrutiny in the Patent and Trademark Office that they receive in subsequent court challenges. PTO proceedings are conducted *ex parte*, and the PTO is simply overwhelmed: "With yearly application totals approximating 300,000, they arrive at a rate of about 1,000 each working day." FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, at Ch. 5 p. 4 (Oct. 2003), *available at http://ftc.gov/os/2003/10/innovationrpt.pdf*. Examiners must act quickly on these applications: "new examiners have 25 hours, and more experienced examiners have 20 hours, to examine a biotechnology patent." *Id.* at Ch. 1 p. 34.

The circumstances are radically different when the validity of a patent is challenged in court, where the proceedings are *inter se*, the court hears from opposing experts, and the issues generally receive as much time and attention as is necessary. The result is that, despite the statutory presumption of validity, 35 U.S.C. § 282, nearly half of all litigated patents are found to be invalid or unenforceable. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 206 (1998).

Against this background, courts could invoke several different possible benchmarks to determine the "but-for" amount of competition when the patentee has paid the challenger to drop the challenge and restrict competition:

First, a court could engage in a case-by-case, *ex-post* determination of patent validity and infringement as part of the subsequent antitrust case. A panel of the Eleventh Circuit appeared to require something like this in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). That Court held that an appropriate

antitrust analysis of exclusion payments requires "an identification of the protection afforded by the patent and the relevant law and consideration of the extent to which the agreements reflect a reasonable implementation of these." *Id.* at 1312. Identifying the "protection afforded by the patent" includes "consider[ation] . . . of the likelihood of the [patentee's] obtaining such protections." *Id.* On remand in *Valley Drug*, the district court conducted an exhaustive analysis of the merits of the underlying patent case and concluded that the patentee was not likely to have obtained the protection that the exclusion payments bought. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1298, 1307 n.26 (S.D. Fla. 2005). The agreement was to that extent unlawful. *Id.*

This potential baseline is subject to significant criticism. Permitting *any* type or form of settlement of a patent challenge is economically efficient only to the extent that the settlement saves litigation costs. Those costs are not saved if resolution of the patent issues is merely deferred to the subsequent antitrust case. Moreover, the deferral of the patent issues is likely to result in a significant temporal extension of the monopoly, as well as the substitution of a less capable challenger. *See* Keith Leffler et al., *Efficiency Trade-Offs In Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F.L. Rev. 33, 54-55 (2004) [hereinafter *"Efficiency Trade-Offs"*].

Second, courts could assume that the patent would be found to be invalid or not infringed. In the pharmaceutical industry, such an assumption is supported by the generic challengers' 73% success rate. Under this baseline, any settlement that restricted generic entry for any time or in any way would be presumptively anticompetitive. The problem with this potential baseline is that this Court has repeatedly admonished that antitrust cases should be based on marketplace realities, not legal presumptions: "[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992). And

although the patentees' success rate in Hatch-Waxman cases (27%) is miserable, it is not zero.

A *third* potential baseline is the patent litigants' own view of the likely outcome of the litigation, as reflected in their objective conduct. Economists use the established economic concept of "expected," *i.e.* probability-adjusted, outcomes of litigation[3] to show that the proper baseline is the amount of competition that *the parties themselves* believed, *as of the time of the agreements*, was *probable*. *See* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1758 (2003) [hereinafter "*Anticompetitive Settlement*"] (proper baseline is the "competition that the patentee could . . . expect *ex ante* to exclude after trial"); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. of Econ. 391, 395 (Summer 2003) [hereinafter "*Antitrust Limits*"] ("A patent settlement cannot [lawfully] lead to lower expected consumer surplus than would have arisen from ongoing litigation"). The patentee would not make a payment to the challenger unless the payment reduced competition to a level below that otherwise expected by the patentee to result from the litigation. Likewise, when the challenger requires a payment in order to agree to the entry date or royalty rate offered by the patentee, that date or rate must provide less competition than the challenger himself expects under litigation. Shapiro, *Antitrust Limits*, at 407-08; Hovenkamp, *Anticompetitive Settlement*, at 1759. This baseline takes account of the key marketplace fact that patent litigation is inherently uncertain; it focuses on the facts as of the date of the agreement; it acknowledges that the patent litigants themselves are best situated to assess the likely outcome of the litigation; and it does not require a relitigation of the patent case.

The Court used this baseline in *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931), where the parties settled

3. *See* William M. Landes, *An Economic Analysis of Courts*, 14 J. L. & Econ. 61 (1971).

a patent litigation over blocking patents by entering into a cross-license ~~agreement.~~ The Court held that the agreement was lawful because it presumably reflected "a division of royalties according to *the value attributed by the parties* to their respective patent claims. . . ." *Id.* at 171 (emphasis added); *see also Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (exclusionary power of pending patent application "depends on how likely the parties consider it to be that a valid patent will issue").

With respect to exclusion payments, the Sixth Circuit has also adopted this competitive baseline. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). In *Cardizem* the patentee paid the challenger to stay out of the market pending resolution of the patent litigation (the Hatch-Waxman Act automatic 30-month stay, 21 U.S.C. § 355 (j)(5)(B)(iii), had expired). Relying on marketplace realities, the Court held that a brand manufacturer's patent does not create an "'impenetrable' legal impediment to [the generic challenger's] production and sale of its FDA-approved generic product." *Cardizem*, 332 F.3d at 914. If the "independent durability of [the brand manufacturer's] patent and the validity of its infringement claim" had been sufficient on their own to exclude a generic competitor from the market, then the brand manufacturer "would not have paid [the generic competitor] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. The patentee's payments gave it something that the patent did not — a "guarantee[]" against competition. *Id.* at 907.

The D.C. Circuit adopted the same baseline in *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) ("Although its *unilateral* decision not to market its generic version of Cardizem CD would have [presumably been lawful], the counterclaim alleges that Andrx entered into an anticompetitive *agreement* with HMRI in order to exclude others; HMRI's $10 million quarterly payments were presumably in return for something that Andrx would not

otherwise do, that is, delay marketing of its generic.") (emphasis in original). So did a unanimous FTC in *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 at 17 (FTC Dec. 8, 2003) ("[I]f there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

A *fourth* potential baseline is for the court applying antitrust law to assume that no competition was likely to result from the patent litigation — to assume that the patent is valid and infringed. This is essentially the baseline adopted here by the Second Circuit, which held that exclusion payments are per se lawful unless the antitrust claimant proves that the underlying patent was procured by fraud or that the patent litigation was a sham. Pet. App. at 51a - 52a. According to the Second Circuit, a patent grants to its holder a "right to exclude," which can be enforced by the patentee by paying the generic firm to withdraw its challenge to the patent. *Id.* at 28a. This is justified, according to the Second Circuit, by the rebuttable presumption of validity, 35 U.S.C. § 282. *See* Pet. App. at 48a-49a.

As noted above, this Court has repeatedly cautioned that antitrust cases must be resolved based on marketplace realities, not on formalistic assumptions. The fact that pharmaceutical patentees have lost 73% of the patent challenges would seem to rule out the Second Circuit's formalistic assumption that patentees will almost always win.

Moreover, there is no presumption of infringement. So the Second Circuit's analysis, which is founded on the presumption of validity, could not justify exclusion payments when the generic firm's challenge is based on non-infringement rather than invalidity. Nor could the Second Circuit's analysis support

the lawfulness of exclusion payments when, as is often the case, the challenge asserts that the patent is invalid if construed broadly and not infringed if construed narrowly.

The impracticality of the Second Circuit's presumption-based approach is highlighted by the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The thrust of the generic firm's challenge in *Schering* was noninfringement rather than invalidity. The Eleventh Circuit expressly recognized the impracticality of making the lawfulness of exclusion payments "turn[ ] on validity ... as opposed to infringement." *Id.* But instead of concluding that a presumption-based approach was therefore unworkable, the Court solved the problem by inventing a presumption of infringement. According to the Eleventh Circuit, "[b]y virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products ... did not infringe Schering's patent." *Id.* at 1066-67. This is the legal abyss into which the Second Circuit's presumption-based approach inevitably leads.

* * * *

In all of the exclusion payment cases, the amount of competition that occurred under the agreements is known. The dispositive issue in each case is the "but-for" amount of competition against which the actual competition is compared. The Circuits are irreconcilably split as to the appropriate competitive baseline.

II. The Issue Is One Of Enormous Importance To Consumers.

Rarely is there as direct a connection between a judge-made rule and a profound effect on consumers as there is in this case. The reality is simple: if exclusion payments are lawful, pharmaceutical patentees will use them to terminate patent challenges that would otherwise generate *billions* of dollars in

consumer savings. These consequences to consumers — consequences to which the Second Circuit was completely inattentive — warrant review by this Court.

The enormous consumer gains resulting from generic entry are shown by a few examples. In the midst of Barr Laboratories' challenge to the patents protecting Eli Lilly's drug Prozac, Barr stated that it would settle only if the agreement included an exclusion payment of at least $200 million. *See* Bethany McLean, *A Bitter Pill*, Fortune, Aug. 2001, at 5. Lilly refused the demand because, as acknowledged by Lilly's CEO, "such a settlement violated antitrust laws, and it isn't morally right." *Id.* So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated $2.5 billion.

By way of another example, a district court ruled that Apotex did not infringe GlaxoSmithKline's patent on its blockbuster drug, Paxil. *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1052 (N.D. Ill. 2003). Apotex launched its generic Paxil product in September 2003, while the district court ruling was on appeal and more than three years before the patent was slated to expire. In April 2005, the Federal Circuit affirmed the judgment in favor of Apotex. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1334 (Fed. Cir. 2005). Early entry of generic Paxil saved consumers more than $ 2 billion.

None of these consumer savings would likely have occurred if the Second Circuit's ruling had been the law at the time. If exclusion payments are permissible under the antitrust law — if the CEOs of Lilly and the other manufacturers are told that they are *wrong* to believe that an exclusion payment settlement "violate[s] antitrust laws, and it isn't morally right" — such settlements will very likely become the norm.

The vast majority of pharmaceutical patent cases can be settled. Leffler, *Efficiency Trade-Offs*, at 42. Of the cases that

can be settled, both the brand and generic manufacturer have a strong economic incentive to divide the monopoly profits between themselves by means of an exclusion payment rather than to share those profits with consumers by means of licensed generic entry. *Id.* at 44. Licensed entry gains far less profits for the generic than it loses for the brand, and consumers get the difference. Both parties' economic incentive, therefore, is for the brand to simply pay the generic and split the amount that licensed entry would have brought to consumers.

This economic analysis was dramatically confirmed by recent events. In connection with a consent decree obtained in one of the early exclusion payment cases, the FTC announced that it would henceforth aggressively prosecute exclusion payment pharmaceutical settlements. *Abbott Labs. and Geneva Pharms.*, No. C-3945, (FTC Mar. 16, 2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary), *available at http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm.* Pharmaceutical manufacturers responded by no longer settling with exclusion payments. Instead, they settled at the same rate as they had before, but they did so the traditional way — with early-entry licenses. *See* FTC, *Prepared Statement of the Federal Trade Commission*, at 13 (Jan. 17, 2007), *available at http://www.ftc.gov/speeches/leibowitz/07170/oralstatement.pdf*. But then came the Eleventh Circuit's decision in *Schering* and the Second Circuit's decision here. The pharmaceutical manufacturers' response was swift and dramatic: in fiscal 2006, 9 of the 11 Hatch-Waxman litigation settlements with generic "first filers" included exclusion payments. *Id.* at 17. If the Second Circuit view prevails, *all* Hatch-Waxman cases that can be settled will likely be settled with exclusion payments — and the patent-challenge provisions of the Hatch-Waxman Act will be eviscerated.

While ignoring these consequences of holding exclusion payments to be lawful, the Second Circuit invented non-existent consequences of holding them to be unlawful. According to the

Second Circuit, permitting exclusion payments is necessary for society to save the costs of patent litigation. *See* Pet. App. at 50a. Three facts undercut the Court's assertion.

First, exclusion payments do not save any litigation costs to the extent that the payments merely defer rather than terminate litigation over the patent's validity. For example, here the patentee litigated the patent case through a judgment from the district court, and only then (having lost) used the exclusion payments to obtain a settlement. *Id.* at 10a. Other generic firms then challenged the patent's validity, but did not get to the same procedural point until four years later. *Id.* at 13a. Thus, the exclusion payments here *multiplied* the patent litigation costs while significantly delaying resolution of patent validity.

Second, the Second Circuit asserts, without citation or analysis, that prohibiting exclusion payments would be tantamount to prohibiting "all, or nearly all, settlements of Hatch-Waxman infringement actions." *Id.* at 50a. Economic analysis shows, however, that exclusion payments are not necessary to achieve any substantial number of efficient settlements. *See, e.g.*, Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holders Should Be Per Se Illegal*, 21 Res. L. & Econ. 475, 483-86 (2004). Indeed, exclusion payment settlements were "virtually unheard of" until this recent spate of settlements in the pharmaceutical industry. Hovenkamp, *Anticompetitive Settlement*, at 1757 n.166. Patent litigants historically have settled their cases by means of licensed entry. During the period when the FTC was successfully prosecuting exclusion payment agreements, pharmaceutical manufacturers had no difficulty at all in settling cases without exclusion payments.

Third, even if a rule permitting exclusion payments would save some litigation costs, courts should weigh those saved litigation costs against the lost consumer welfare that would result from propping up weak patents. But the Second Circuit conspicuously failed to make this essential comparison. The fact is that litigation expenses are trivial in comparison to the

lost consumer welfare that results from exclusion payments. *See* Herbert Hovenkamp et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 716-17 (2004) ("while patent litigation is not cheap, it is a tiny fraction of the amount of money that is at stake in the cases we are discussing"); *see also Blonder-Tongue Labs., Inc. v. University of Illinois Fnd.*, 402 U.S. 313, 349 (1971) ("the economic consequences of [permitting the patentee to repeatedly litigate validity] are serious and any reduction of litigation in this context is by comparison an incidental matter").

III. The Second Circuit's Decision Conflicts With Patent Law And The Hatch-Waxman Act.

It is unlawful under the Sherman Act to pay a competitor to restrict competition, including uncertain competition. *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc); XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 2030b at 213 (2d ed. 2005). Here, of course, a court applying antitrust law must take account of the Hatch-Waxman Act regulatory scheme and of the fact that a patent is the source of the uncertainty of the competition. *See Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, L.L.P.*, 540 U.S. 398, 411-12 (2004). The Second Circuit's decision is entirely incompatible with patent law as reflected in no fewer than six of this Court's decisions and with Congress' specific treatment of pharmaceutical patents in the Hatch-Waxman Act.

The *Qualified* "Right to Exclude"

Relying on the rebuttable presumption of validity, the Second Circuit held that the patentee has an absolute "right to exclude" that may be enforced by paying the generic challenger to restrict competition. Pet. App. at 28a; *see also Schering*, 402 F.3d at 1066. Patent law provides no such absolute right to exclude. Instead, Congress provided for plenary judicial determination of the validity of patents. 35 U.S.C. § 282; *see Medimmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007)

(federal courts have jurisdiction to decide patent validity even when the parties have entered into a license and are complying with that agreement). As this Court has explained, "The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969). For example, the Court in *eBay Inc. v. Mercexchange, L.L.C.*, 126 S. Ct. 1837, 1840 (2006), held that even after a court has entered a final judgment finding infringement, the patentee is not automatically entitled to exclude the adjudged infringer, but instead must satisfy the traditional requirements for equitable relief. *See also id.* at 1842 (Kennedy, J., concurring) ("an injunction may not serve the public interest" and the "suspect validity of some of these patents may affect the calculus under the four-factor test").

The presumption of validity relied on by the Second Circuit clearly does not establish an ironclad right to exclude; it "is a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). The presumption merely assigns burdens to litigants in patent trials and cannot "acquire an independent evidentiary role in any [other] proceeding." *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985).

The *qualified* nature of the "right to exclude" is confirmed in the Hatch-Waxman Act, where Congress did grant to patentees a procedure to obtain automatic exclusion of generic challengers, but only for a limited period of time — 30 months. After the expiration of 30 months, the FDA is free to approve a generic drug for marketing regardless of whether patent litigation is ongoing. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Then the patentee can obtain exclusion only the old-fashioned way — by satisfying the requirements for a preliminary injunction, including a showing of likelihood of success on the merits.[4]

4. At the preliminary injunction stage, "the *patentee* carries the burden of showing likelihood of success on the merits with respect to

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Congress' understanding that patents are not ironclad, and that exclusion payment agreements are anticompetitive, was made perfectly clear in the hearings leading up to the pharmaceutical-settlement reporting legislation.[5] *See, e.g.*, 148 CONG. REC. S7566 (daily ed. Jul. 20, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type of reverse payment collusive arrangements appalling"); 146 CONG. REC. E1538-02 (daily ed. Sep. 20, 2000) (remarks of Rep. Waxman) ("requir[ing] companies seeking to reach secret, anticompetitive agreements to disclose them to the FTC ... [will] ensure that existing antitrust and drug approval laws are enforced to the letter"); 147 CONG. REC. S3711 (daily ed. Apr. 6, 2001) (remarks of Sen. Leahy) (legislation is intended to give to the FTC "the information they need to prevent manufacturers of patented drugs — often brand-name drugs — from simply paying generic drug companies to keep lower-cost products off the market").

The Realist View of a "Patent"

The foundation of the Second Circuit's decision is a formalist view of what a "patent" is: a patent issued by the PTO is presumed to be valid and therefore "the patent holder is [permitted to] pay [ ] to protect its patent monopoly." Pet. App. at 38a; *see also Schering*, 402 F.3d at 1068 ("there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude [alleged infringers]"). In contrast,

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the patent's validity." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original); *see also Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994). In pharmaceutical as well as other patent cases, courts applying patent law frequently deny preliminary injunctions on the ground that, until a judicial finding of validity and infringement, the alleged infringer has a "right to compete." *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990).

5. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

this Court has repeatedly taken a realist, clear-eyed view of patents and the patent process. The Court has held:

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.

Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969); *see also Laboratory Corp. of America Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2929 (2006) (Breyer, J., dissenting from dismissal of certiorari) (noting the "ongoing debate . . . as to whether the patent system, as currently administered and enforced, adequately reflects the [balance embodied in the patent laws]"); *eBay*, 126 S. Ct. at 1842 (Kennedy, J., concurring) (courts determining injunctive relief should consider economic and regulatory realities).

The Public Interest

This Court has long noted that "[a] patent by its very nature is affected with a public interest" because of its potentially "far-reaching social and economic consequences." *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816 (1945); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993); *Blonder-Tongue Labs.*, 402 U.S. at 344; *Lear*, 395 U.S. at 670. The Second Circuit asserted that it had safeguarded the public interest by ensuring that the exclusion effected by the payments did not exceed the subject matter or temporal scope of the patent, assuming that the patent was valid and infringed. Pet. App. at 53a - 54a.

But the requirement alluded to by the Second Circuit — that exclusion not exceed the subject matter or temporal scope of the patent — is just "one obvious manifestation" of the principle that patents are affected with a public interest. *Blonder-*

Tongue Labs, 402 U.S. at 343. The Second Circuit ignored a second aspect of the principle — "[a] second group of authorities [that] encourage authoritative testing of patent validity." *Id.* at 344. Although patents carry a rebuttable presumption that the PTO appropriately granted the patent, *id.* at 335, "Congress has from the outset chosen to impose broad criteria of patentability while lodging in the federal courts final authority to decide that question," *id.* at 332.

Accordingly, this Court has held that a patentee cannot "muzzle[]" those who otherwise have an "economic incentive to challenge the patentability of an inventor's discovery." *Lear*, 395 U.S. at 670. That conclusion is in significant tension with the Second Circuit's endorsement of a contractual provision that simply pays the patent challenger to withdraw the challenge.

With respect to pharmaceutical patents, Congress underscored the overriding public interest in avoiding unwarranted patent-based monopolies by providing a 180-day exclusivity bounty for generic entry via patent challenges. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The courts have guarded against statutory interpretations that would "diminish[] the incentive for the manufacturer of generic drugs to challenge a patent ... in the hope of bringing to market a generic competitor." *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) (invalidating FDA rule that would have such an effect). A payment by the patentee to the generic challenger to stay out of the market is, of course, the ultimate way to "diminish[] the incentive for a [generic firm] ... [to] bring[] to market a generic competitor." *Id.*

The Initial Finding of Invalidity

The conflict between the Second Circuit's decision and this Court's patent-law precedents is heightened by the fact that the patentee here made the exclusion payments after the district court in the underlying patent litigation had already found the patent to be invalid. *See Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 2d 619 (S.D.N.Y. 1992). That court

made key factual findings against the patentee, *id.* at 626-27, which were entitled to substantial deference on appeal. By paying off the generic challenger that had obtained the fact-driven district court judgment, the patentee wiped the factual slate clean and was able to start again against a different set of challengers. *See* Pet. App. at 12a (settlement was contingent on vacatur of district court judgment).

In contrast, this Court rejected the Federal Circuit's former practice of vacating declaratory judgments of invalidity following an appellate determination of non-infringement. *Cardinal Chemical Co.*, 508 U.S. at 102. Vacating district court judgments of invalidity "encourages endless litigation (or at least uncertainty) over the validity of outstanding patents." *Id.* Moreover, the practice tends to "multiply the opportunities for holders of invalid patents" to try to enforce them, which is particularly improper because "[i]n each successive suit the patentee enjoys the statutory presumption of validity." *Id.* at 101 n.24 (quoting *Blonder-Tongue*, 402 U.S. at 342, 338). Here the Second Circuit permitted the patentee to buy from its would-be competitor the very "multipl[e] . . . opportunities" that this Court has condemned as against public policy.

The Significance of Delay

The Second Circuit suggested that its decision is consistent with the vital policy of avoiding unwarranted patent-based monopolies because an exclusion payment made to the first generic challenger will simply invite additional challenges to the patent by other generic firms. *See* Pet. App. at 49a. The Court reached that conclusion even though the exclusion payments here resulted in a four-year delay in the judicial testing of the patent. *See id.* at 10a (exclusion payments made in March 1993, while litigants were awaiting a Federal Circuit ruling); *Zeneca Ltd. v. Novapharm Ltd.*, 111 F.3d 144 (Fed. Cir. 1997) (subsequent generic challengers did not receive Federal Circuit ruling until April 1997). Nor is this delay unusual in the pharmaceutical industry, which has substantial regulatory

barriers to generic entry. *See Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (noting "particularly high barriers to entry resulting . . . from the regulatory requirements to sell generics"); Herbert Hovenkamp et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 7.4 at 7-37 (2006 Supp.) (due to regulatory barriers, exclusion payments made to first generic challenger "can delay entry by another generic for three years or more"). Exclusion payments will presumably always result in economically meaningful delay — otherwise the patentee would not make them. This Court has carefully guarded against such delay. *See, e.g., Lear*, 395 U.S. at 673 (prohibiting practice that "would give the licensor an additional economic incentive to devise every conceivable dilatory tactic in an effort to postpone the day of final judicial reckoning"); *Cardinal Chem. Co.*, 508 U.S. at 102 (prohibiting practice that "prolongs the life of invalid patents").

* * * *

In *Bonito Boats, Inc. v. Thundercraft Boats, Inc.*, 489 U.S. 141 (1989), the Court held that the State of Florida could not properly create patent-like rights that are broader than those embodied in the federal patent law. Such non-federal exclusionary rights are impermissible because "the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Id.* at 146; *see also Laboratory Corp.*, 126 S. Ct. at 2922 (Breyer, J., dissenting from dismissal of certiorari) ("patent law seeks to avoid the damage of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten").

Imagine if, instead, Florida enacted a statute providing that its courts would grant preliminary and permanent injunctive relief in favor of patentees without inquiry into the validity of

the patent (or inquiry limited to whether the patent was so obviously invalid as to render attempted enforcement a "sham"). Imagine further that Florida attempted to justify its statute on the grounds that patents once issued by the PTO are presumed to be valid and that the policy of the federal government is to save litigation costs. Against the background of this Court's patent precedents, is it not clear that Florida's attempts to justify its statute would be met with incredulity? And would not the incredulity turn to astonishment if the Florida statute purported to apply even after a federal district court had found a patent to be invalid?

Yet the Second Circuit's decision here permits private parties to do exactly what no State would be permitted to do. That decision is irreconcilable with this Court's fundamental patent precedents and with the Hatch-Waxman Act, and the Court should therefore grant review.

CONCLUSION

NACDS respectfully submits that this Court should grant certiorari to resolve a Circuit split on a matter of enormous consequence to consumers, and to conform the law on this issue with the Court's patent-law precedents and the Hatch-Waxman Act.

Respectfully submitted,

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